

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**  
(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.  
**15827 (PC25075A)**

In Re Application Of: **David Scott McVey**

MAR 08 2004

Serial No.

10/714,679

Filing Date

November 14, 2003

Examiner

Unassigned

Group Art Unit

Unassigned

Title: **USE OF A RMLT AS A MARKER ANTIGEN FOR VACCINES AND AS A SYNERGISTIC  
ADJUVANT WITH AMPHIGEN**

Address to:

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**37 CFR 1.97(b)**

1. ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

**37 CFR 1.97(c)**

2. ☐ The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:

- ☐ the statement specified in 37 CFR 1.97(e);

**OR**

- ☐ the fee set forth in 37 CFR 1.17(p).

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**USE OF A RMLT AS A MARKER ANTIGEN FOR VACCINES AND AS A SYNERGISTIC  
ADJUVANT WITH AMPHIGEN****Payment of Fee**

(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))

- ☐ A check in the amount of \_\_\_\_\_ is attached.
- ☒ The Director is hereby authorized to charge and credit Deposit Account No. **19-1013/SSMP** as described below.
- ☐ Charge the amount of \_\_\_\_\_
- ☒ Credit any overpayment.
- ☒ Charge any additional fee required.

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_____ Signature of Person Mailing Correspondence	
Peter I. Bernstein	
_____ Typed or Printed Name of Person Mailing Certificate	

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\_\_\_\_\_  
Signature

Dated: **March 4, 2004**

Peter I. Bernstein  
SCULLY, SCOTT, MURPHY & PRESSER  
400 Garden City Plaza  
Garden City, NY 11530  
(516) 742-4343

PIB:ahs/dg

CC:



**THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**Applicant:** David Scott McVey                      **Examiner:** Unassigned  
**Serial No:** 10/714,679                      **Art Unit:** Unassigned  
**Filed:** November 14, 2003                      **Docket:** 15827 (PC25075A)  
**For:** USE OF A RMLT AS A MARKER                      **Dated:** March 4, 2004  
ANTIGEN FOR VACCINES AND AS  
A SYNERGISTIC ADJUVANT WITH  
AMPHIGEN

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Sir:

In accordance with 37 C.F.R. §§ 1.97 and 1.98, it is requested that the following references, which are also listed on the attached Form PTO-1449, be made of record in the above-identified case.

1. United States Patent No. 6,309,845 B1, dated October 30, 2001, issued to Gareis, et al.;
2. German Patent No. 198 47 118 C2, dated May 4, 2000, together with English-language translation;
3. Carol L. Pickett, et al., "Genetics of Type IIa Heat-Labile Enterotoxin of *Escherichia coli*: Operon Fusions, Nucleotide Sequence, and Hybridization Studies", Journal of Bacteriology, 169(11):5180-5187 (1987);

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**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on March 4, 2004.

Dated: March 4, 2004

  
Peter I. Bernstein

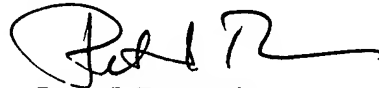
4. Stephen Harford, et al., "Inactivation of the *Escherichia coli* Heat-Labile Enterotoxin by *in vitro* Mutagenesis of the A-subunit Gene", Eur. J. Biochem, 183:311-316 (1989);
5. Takao Tsuji, et al., "A Single Amino Acid Substitution in the A Subunit of *Escherichia coli* Enterotoxin Results in a Loss of Its Toxic Activity", The Journal of Biological Chemistry, 265(36):22520-22525 (1990);
6. United States Patent No. 6,019,982, dated February 1, 2000, issued to Clements, et al.;
7. United States Patent No. 6,033,673, dated March 7, 2000, issued to Clements;
8. United States Patent No. 6,149,919, dated November 21, 2000, issued to Domenighini, et al.;
9. United States Patent No. 5,182,109, dated January 26, 1993, issued to Tamura, et al.;
10. John D. Clement, et al., "Adjuvant Activity of *Escherichia coli* Heat-labile Enterotoxin and Effect on the Induction of Oral Tolerance in Mice to Unrelated Protein Antigens", Vaccine, 6:269-277 (1988); and
11. American Society of Microbiology, "Abstracts of the Annual Meeting", May 1988.

Applicant is submitting copies of the above-cited references.

Consideration of this Information Disclosure Statement is respectfully requested, since the art provided may be material to the examination of the present application as defined under 37 C.F.R. §1.56.

Inasmuch as this Information Disclosure Statement is being submitted in accordance with the schedule set out in 37 C.F.R. § 1.97(b), no statement or fee is required.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Peter I. Bernstein", with a stylized flourish at the end.

Peter I. Bernstein  
Registration No. 43,497

Scully, Scott, Murphy & Presser  
400 Garden City Plaza  
Garden City, New York 11530  
(516) 742-4343

PIB:ahs/dg



